

Product Information

VESTAKEEP® iC 4506 R

STOCK SHAPES BASED ON X-RAY OPAQUE POLYETHER ETHER KETONE FOR LONG TERM IMPLANTABLE MEDICAL DEVICES



VESTAKEEP® iC4506 R is a rod stock based on implantable grade polyether ether ketone resin VESTAKEEP® iC4506 G. It contains 6% barium sulphate to render it X-ray opaque.

Proven Biocompatibility

VESTAKEEP® iC4506 R is especially designed for long term implantable medical devices.

The compound composition is optimised for high biocompatibility and mechanical, thermal and chemical resistance.

Biocompatibility of VESTAKEEP® iC4506 R has been tested following ISO 10993-1 recommendations for permanent tissue/bone contact and USP Class VI.

A summary of biocompatibility test results is available upon request.

Biocompatibility reports available for VESTAKEEP® iC4506 R

STANDARD	DESCRIPTION
ISO 10993-12	GC/MS Fingerprint of extractable organic substances
USP CLASS VI	Acute Systemic Toxicity Intracutaneous Reactivity Muscle Implantation
ISO 10993-5	Cytotoxicity
ISO 10993-10	Irritation: Intracutaneous Reactivity
ISO 10993-10	Sensitization: Maximization test according to Magnusson and Kligman
ISO 10993-11	Subchronic Systemic Toxicity
ISO 10993-3	Genotoxicity: Ames Test
ISO 10993-3	Genotoxicity: Chromosome Aberration test
ISO 10993-3	Genotoxicity: Mouse Lymphoma test
ISO 10993-6	Test for local effects after Implantation in bone (180 days)
ISO 10993-11	Material-mediated pyrogenes

Delivery of VESTAKEEP® i-Grades

VESTAKEEP® iC4506 R is supplied as stock shapes with 20 mm diameter and a length of 3000 mm and with a diameter of 40 mm and a length of 2000 mm. Other diameters and lengths are possible.

The results shown have been generated from a low number of production lots. Therefore, they are preliminary and not yet the result of a statistical evaluation. Therefore they must not be used to establish specifications.

The values presented are typical or average values, they do not constitute a specification.

Key Features
Industrial Sector

Medical Devices

Processing

Machining

Delivery form

Stock shape (rods and plates)

Optics

Opaque

Resistance to

Heat (thermal stability), Hydrolysis / hot water, UV / light / weathering

Electrical

Insulating

Conformity

Biocompatibility, Medical application

Additives

Mineral fillers

Mechanical properties ISO

	dry	Unit	Test Standard
Tensile modulus	4200	MPa	ISO 527
Tensile strength	109	MPa	ISO 527
Yield stress	109	MPa	ISO 527
Yield strain	4.6	%	ISO 527
Strain at break, B	10	%	ISO 527
Izod Impact notched, 23°C	5.4	kJ/m ²	ISO 180/1A
Type of failure	C	-	-
Flexural modulus, 23°C	4200	MPa	ISO 178
Flexural strength, 23°C	170	MPa	ISO 178

Thermal properties

	dry	Unit	Test Standard
Melting temperature	340	°C	ISO 11357-1/-3
Glass transition temperature, 2 nd heating, onset	145	°C	ISO 11357
Glass transition temperature, 2 nd heating, midpoint	155	°C	ISO 11357
Recrystallization temperature, 10 K/min	285^[e]	°C	ISO 11357
Melting Temperature	340	°C	ASTM D 3418

e: 20 K/minute

Physical properties

	dry	Unit	Test Standard
Density	1350	kg/m ³	ISO 1183
Water absorption	0.4	%	Sim. to ISO 62
Density	1350	kg/m ³	ASTM D 792

Characteristics

Applications

Medical implants

Special Characteristics

Phosphorus-free, PTFE-free, High impact strength, Semi-crystalline, High viscosity, Self-extinguishing

Features

Low odor, Non-corrosive

Color

Natural color

Additives

Inorganic fillers

Chemical Resistance

Acid resistance, Solvent resistance, Oxidation resistance, Radiation resistance, General chemical resistance